

### **REMARKS**

Favorable reconsideration of applicants' pending claims is respectfully requested in view of the above amendments and following remarks. Following the amendments, claims 1-13, 16-21 and 23-55 are pending in the application, with claims 1, 6 and 18 being in independent format.

Claims 14, 15 and 22 have been cancelled from the application, and claims 29-55 have been added. Claim 1 has been amended to incorporate subject matter previously recited in claims 14 and 15. More specifically, claim 1 has been amended to recite that the claimed interventional catheter system comprises an operating head that is adjustable between two different operating diameters and that the control pod incorporates a selection switch that allows an operator to select between the two operating head diameters. Newly added claim 29, which is dependent upon claim 1, is drawn to such a system wherein the selection switch changes the direction of rotational output of the drive system. Support for these amendments may be found, for example, at page 13, lines 4-7, of the specification as originally filed.

Claims 6 and 18 have been rewritten in independent format. In addition, claim 18 has been amended to recite that the actuator is positioned distally to the control pod. It is submitted that support for this amendment may be found, for example, in Fig. 1 of the application as originally filed. Newly added claims 30-42 and 43-55 which are dependent on claims 6 and 18, respectfully, mirror the subject matter of claims 2, 4, 5, 8-12, 16, 19, 24, 25 and 27.

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter or raise new issues for consideration.

### **Claim Rejections – §102(b)**

Claims 1, 2, 5, 9, 12, 16-22 and 24-28 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wulfman et al., U.S. Patent Publication US 2002/0007190. This rejection is respectfully traversed, particularly in view of the above amendments and following remarks.

As discussed above, independent claim 1 has been amended to recite that the operating head of the claimed interventional catheter assembly is adjustable between two different operating diameters and that the control pod incorporates a selection switch that allows an operator to select between the two operating head diameters. Wulfman et al. do not teach or

suggest a catheter assembly having a control pod with a selection switch that permits the operator to select between two different operating head diameters. Nor do they teach or suggest that the selection switch changes the direction of rotational output of the drive system (and thus the direction of rotation of the operating head) as recited in newly added claim 29. It is this change in the rotational direction of the operating head that leads to the change in its diameter.

With regard to claim 2, applicants note that while Wulfman et al. teach the use of a direct current variable speed micro-motor, they do not teach or suggest the use of a motor that delivers a constant voltage for any specified rotational output, as clearly stated in the claim. Applicants note that, in order for a reference to be prior art under §102, each and every feature recited in the claim must be taught by the prior art reference.

With regard to claims 9 and 25, Wulfman et al. teach the use of a vacuum pump, but do not teach or suggest the use of a multi-lobed pump. As outlined at page 9, lines 19-27, of the present specification, there are significant advantages to using a multi-lobed pump.

Claim 18, which has been amended to independent format, recites an interventional catheter assembly comprising, among other components, a sliding actuator mounted on the catheter system distally to the control pod and coupled to the drive motor such that the drive motor is actuated when the sliding actuator grips the catheter system and advances it. The Examiner asserts that Fig. 2 of Wulfman et al. discloses a drive motor coupled to a sliding actuator mounted on the catheter system. Applicants respectfully disagree. As stated in paragraph 007 of the reference, Fig. 2 of Wulfman et al. illustrates an advancer system, or "tracking unit" for axially translating the drive shaft and associated components. There is no disclosure of actuation of the drive motor when a sliding actuator grips the catheter system, nor is there any suggestion of any such feature.

Claim 20 is drawn to an assembly including a guidewire brake control system interrupt that prevents the drive system from being actuated when the guidewire brake is in a release position, i.e. when the guidewire is able to move. Claim 21 is drawn to an assembly comprising a guidewire brake selectable interrupt override control that permits an operator to selectably permit operation of the drive system when the guidewire brake is in a release position. The operation of the control system interrupt and the selectable interrupt override control are detailed on page 17, lines 11-21, of the instant specification. The Examiner asserts that Wulfman et al.

teach a guidewire brake system that selectably prevents actuation of the drive system. Applicants respectfully submit that Wulfman et al. in fact teach a guidewire brake system (22) and a *separate* locking mechanism that restricts axial movement of the motor assembly 506. Wulfman et al. do not teach or suggest a brake system that controls both movement of the guidewire *and* actuation of the drive system, nor do they teach or suggest an override control that allows an operator to selectably permit operation of the drive system when the guidewire brake is released.

It is urged that Wulfman et al. neither teach or suggest the subject matter of the claims 1, 2, 5, 9, 12, 16-22 and 24-28, and that the rejection of the claims under §102(b) may thus be properly withdrawn.

**Claim Rejections – §103(a)**

Claims 3, 4, 6-8, 10, 11, 13-15, 23 and 26 stand rejected under 35 USC §103(a) as being obvious over Wulfman et al. in view of various prior art references, as detailed below. These rejections are respectfully traversed in view of the above amendments and the following remarks.

Claim 3 stands rejected as being unpatentable over Wulfman et al. in view of US 5,358,509 to Fine et al. Specifically, the Examiner states that Fine et al. “teaches adjusting the rotation and speed based on the load requirements by altering the current and voltage of the motor.” However, Fine et al. does not overcome the deficiencies of Wulfman et al. discussed above with respect to claim 1.

Claim 4 stands rejected as being unpatentable over Wulfman et al. in view of US 3,374,425 to Barditch et al. Specifically, the Examiner states that Barditch et al. teaches “a cascaded power supply for producing a clean dc output.” Barditch et al. does not overcome the deficiencies of Wulfman et al. discussed above. Indeed, Barditch et al. is not concerned with interventional catheter systems.

Claims 6 and 7 stand rejected as being unpatentable over Wulfman et al. in view of US 5,921,956 to Grinberg et al. As noted by the Examiner, Wulfman et al. does not disclose a torque selection feature. The Examiner asserts that it would have been obvious to combine the disclosure of Wulfman et al. with the teachings of Grinberg et al. to provide torque control.

Grinberg et al. teach a surgical instrument that includes a steerable surgical tool, such as a cutting implement, together with a motor whose operation, for example, speed, torque and

direction of rotation, is controlled by a control unit. Grinberg et al. do not teach or suggest a control unit including a feature that provides, and thus permits an operator to select between, different *preselected* torque levels, as recited in claim 6. Nor do Grinberg et al. overcome the deficiencies of Wulfman et al. discussed above.

Claim 8 stands rejected as being unpatentable over Wulfman et al. in view of US 5,795,325 to Valley et al. Valley et al. disclose a device for reducing migration of occluding members used to establish cardiopulmonary bypass during surgery to repair heart valves, for example. In certain embodiments, the device includes a coaxial-construction catheter including an inner and an outer tube. Valley et al. state that either or both of the tubes “may be reinforced with wire or filament braiding or coils for increased stiffness, torque control or kink resistance.” The reference does not teach or suggest a catheter comprising at least one section wherein a coil contacts but *is not bonded to* the catheter as recited in present claim 8. As discussed in the instant specification at page 18, line 26 - page 19, line 3, this allows the coil and the catheter to flex independently of one another, thereby reducing kinking while maintaining flexibility. In addition, Valley et al. do not overcome the deficiencies of Wulfman et al. discussed above.

Claims 10 and 26 stand rejected as being unpatentable over Wulfman et al. in view of US 6,258,111 to Ross et al. Specifically, the Examiner states that the reference “teaches a surgical cutting system with an aspiration system comprising a plurality of vacuum pumps.” Applicants respectfully note Ross et al. state that their vacuum control system contains a plurality of vacuum sources connected *in parallel* with a vacuum reservoir and a cutter (col. 8, lines 39-42). Thus Ross et al. do not teach an aspiration system comprising a plurality of vacuum pumps connected *in series*, as recited in claims 10 and 26. Nor do they overcome the deficiencies of Wulfman et al. discussed above.

Claim 11 stands rejected as being unpatentable over Wulfman et al. in view of US 6,080,170 to Nash et al. The Examiner asserts that Nash et al. teach a drive assembly including a drive shaft connected to a drive motor through a ball bearing assembly, wherein the ball bearing assembly comprises “an outer tube with the drive shaft slidably held within the outer tube by balls.” Nash et al. teaches an atherectomy catheter including, at its proximal end, a ball bearing assembly into which extends the proximal end of a turbine drive shaft (col. 21, lines 60-61, and col. 22, lines 36-38). It is submitted that Nash et al. do not teach or suggest a control pod that

houses a drive motor coupled to a drive shaft by sliding tubes that rotate with respect to one another by means of balls held in slots formed in the tubes, as recited in claim 11. Furthermore, Nash et al. do not overcome the deficiencies of Wulfman et al. discussed above.

Claims 13-15 stand rejected as being unpatentable over Wulfman et al. in view of US 5,318,576 to Plassche, Jr. et al. The Examiner asserts that the reference teaches a surgery system comprising an operable head, in which the speed and diameter of the head is controlled via switches in a control pod. As noted above, claims 14 and 15 have been cancelled from the application, and claim 1 has been amended to include the subject matter previously recited in these claims.

The disclosure of Wulfman et al. is discussed above. Plassche, Jr. et al. teach a system comprising a cutter that can be shortened between its distal and proximal ends, and thus radially expanded, by pulling on a guidewire extending through the cutter. The system includes a control unit with an OFF/ON switch and a rotational speed control that adjusts the rotation of a drive shaft. The reference states that the cutter “is expanded by pulling on the guidewire 30 using pulling means in a controller” (col. 5, lines 18-20). Applicants submit that neither Wulfman et al. nor Plassche, Jr., et al., taken either singly or in combination, teach or suggest an interventional catheter system comprising an operating head that is adjustable between two different operating diameters and a control pod incorporating a selection switch that allows an operator to select between the different operating diameters, as recited in amended claim 1. Nor do the references teach or suggest such a system wherein the selection switch changes the direction of rotation of the drive system (and thus the operating head), as recited in newly added claim 29.

Claim 23 stands rejected as being unpatentable over Wulfman et al. in view of US 6,398,755 to Belef et al. The Examiner asserts that Belef et al. teach an “extendable, telescoping guidewire support (51) mounted on a drive sled (26).” Applicants respectfully disagree. As discussed at col. 4, line 54 – col. 5, line 19 of the reference, Belef et al. teach a drivable catheter assembly including a catheter drive unit (22), and a catheter (24) housed within a catheter sheath (36). The catheter sheath includes a telescoping portion (51) which is attached to the housing of the drive unit. It is thus submitted that Belef et al. neither teaches or suggests a catheter assembly comprising an extendable, telescoping guidewire support mounted in a control pod, as recited in

claim 23. Furthermore, Belef et al. do not overcome the deficiencies of Wulfman et al. discussed above.

It is submitted that none of the cited references, taken either singly or in combination, would have rendered the presently claimed subject matter obvious to one of skill in the art at the time the invention was made, and that the rejection of the claims under 35 USC §103(a) may thus be properly withdrawn.

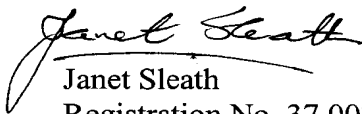
**Conclusion**

In view of the above amendments and remarks, applicants believe that the pending claims are now in condition for allowance. Early consideration and allowance of all the pending claims are respectfully requested.

A Request for a Two Month Extension of Time, extending the deadline for responding to the Office Action to February 14, 2007, is submitted herewith, together with a Request to Correct Inventorship under 37 CFR §1.48(b).

Should the Examiner have any further concerns regarding this application, he is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

  
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